The subject of our application is a culture medium, intended for rapid diagnosis of tuberculosis that detects the growth of mycobacteria earlier than classical mycobacterial culture media. The growth detection in classical mycobacterial culture media depend on the observation of growing colonies on solid medium or turbidity in liquid medium. This takes usually 3 to 6 weeks due to the slow-growing nature of *Mycobacterium tuberculosis*. The principle of early mycobacterial growth detection in our subject invention depends on the pH change that occurs when mycobacteria grow. The original pH of 7.6 of the medium drops to between pH 6.0 and 6.8. The pH indicator dyes included in the medium create the color change of the medium enabling the observation of the pH change, thus indicating the growth. The original red color of the medium changes to yellow as a result of mycobacterial growth. Since the color change occurs before the colonies become visible on the medium, the time required for growth detection is shortened. If contaminants, other bacteria or fungi, grow in the medium these create a bigger pH change in the medium leading to a different color change. The pH drops below 6.0 and the original red color of the medium turns green. The observation of yellow color indicates mycobacterial growth and green color indicates contamination (as shown in the below figure).

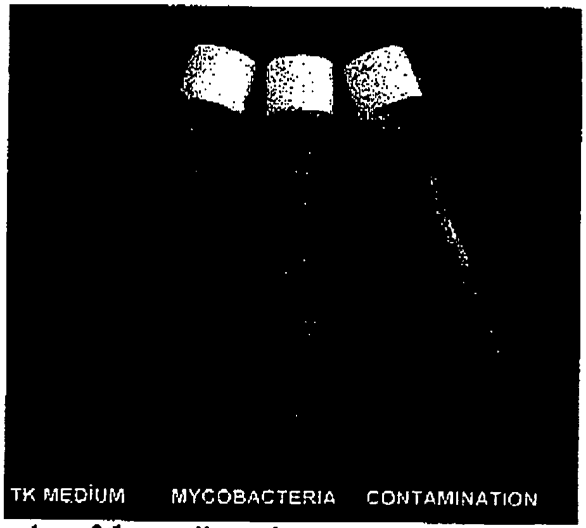

Figure: The original red color of the medium changes to yellow as a result of mycobacterial growth and green as a result of the growth of contaminant organisms.

The summary for the reason for the rejection of claims by the examiner:

All our claims (1-14) filed in our application were rejected by the examiner under 35 U.S.C. 102(b) as being anticipated by Miyamoto et al. (US 6197574 B1) and under 35 U.S.C. 103(a) as being unpatentable over Miyamoto in view of De Haan (WO 00/15045).

The examiner argued that several chemicals that constitute our medium also existed in the media defined by Miyamoto et al. and some that are missing, like albumin (which is essential for mycobacterial growth), may be found in some other medium like the one defined by De Haan. The examiner argued that a new function defined for a prior art may not be subject for a new claim and patent application.

The summary of our response to claim rejections:

We have responded arguing that our rapid mycobacterial culture medium is unique and original in both composition and function. There is no other culture medium that can detect **mycobacterial growth by pH change** using colored pH indicators and at the same time **differentiate mycobacterial growth from contamination** by producing different colors in the case of mycobacterial growth and growth of other organisms.

Many original culture media with a unique function contain similar general chemicals, like agar that is present in almost all solid media and amino acid and essential element sources like peptones, beef extract and yeast extract. Sometimes a difference of a single chemical may completely change the function and features of a culture medium. Although some of the chemicals contained in our mycobacterial culture media are present in the culture media defined by Miyamoto, the latter is not intended to grow mycobacteria, will not grow mycobacteria and will not differentiate it from contamination. Therefore, we are not defining a new function for the culture medium defined by Miyamoto.

Maybe we can clarify the issue by giving a similar example. A disposable plastic syringe and a plastic chair can not be considered the same due to the fact that they both are made up of plastic and some coloring dyes.

Action for resolution of the arguments:

In our application one part of the claim 1 defines the function and features of our rapid mycobacterial culture medium. The other part of claim 1 and the rest of the claims, 2 to 14, mainly define the composition or the function based on this composition.

Since the examiner and the applicant are not convinced by each other's arguments we have decided to withdraw all our claims and part of claim 1 that is related to the composition of our rapid culture medium. We are amending Claim 1 so that it defines only the intended purpose and function of our medium. The remaining claims have all been withdrawn. Please refer to the separate document accompanying this response for specifics of the amendments.

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Date

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